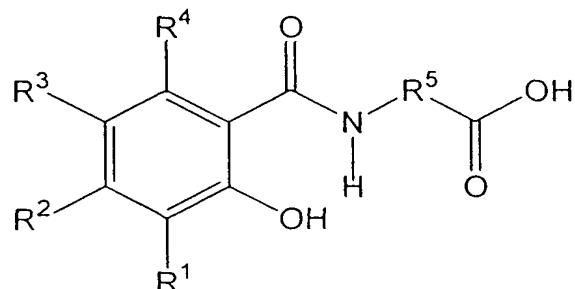


ABSTRACT

5 The inventors have discovered that the disodium salt of certain delivery agents has surprisingly greater efficacy for delivering active agents than the corresponding monosodium salt. Furthermore, the inventors have discovered that the disodium salts of these delivery agents form solvates with ethanol and hydrates with water. The delivery agents have the formula

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wherein

R¹, R², R³, and R⁴ are independently hydrogen, halogen, C₁-C₄ alkyl, or C₁-C₄ alkoxy; and

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R⁵ is a substituted or unsubstituted C₂-C₁₆ alkylene, substituted or unsubstituted C₂-C₁₆ alkenylene, substituted or unsubstituted C₁-C₁₂ alkyl(arylene), or substituted or unsubstituted aryl(C₁-C₁₂ alkylene). The hydrates and solvates of present invention also have surprisingly greater efficacy for delivering active agents, such as heparin and calcitonin, than their corresponding monosodium salts and free acids. The present invention provides an alcohol solvate, such as ethanol solvate, of a disodium salt of a delivery agent of the formula above. The invention also provides a hydrate of a disodium salt of a delivery agent of the formula above. Preferred delivery agents include, but are not limited to, *N*-(5-chlorosalicyloyl)-8-aminocaprylic acid (5-CNAC), *N*-(10-[2-hydroxybenzoyl]amino)decanoic acid (SNAD), and sodium *N*-(8-[2-hydroxybenzoyl]amino)caprylate (SNAC). The invention also provides methods of preparing the disodium salt, ethanol solvate, and hydrate and compositions containing the disodium salt, ethanol solvate, and/or hydrate.

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